Impact of Surgical Approach on Clinical Outcomes in the Treatment of Lumbar Pseudarthrosis

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Abstract

Study Design Retrospective comparative cohort.

Objective Pseudarthrosis following fusion for degenerative lumbar spine pathologies remains a substantial problem. Current data shows that patients who develop a pseudarthrosis have suboptimal outcomes. This study evaluates if treatment of pseudarthrosis can be affected by surgical approach.

Methods Medical records of 63 female and 65 male patients (mean age 50.37) who were treated for nonunion following lumbar fusion were reviewed. Sixty patients underwent posterolateral fusion (PSF), 18 underwent PSF with transforaminal interbody fusion (TLIF), 32 underwent anterior and posterior spinal fusion (AP), and 24 underwent anterior lumbar interbody fusion (ALIF).

Results Significant differences between the treatment groups were observed in length of stay (p=0.000), blood loss (p=0.000), and operative time (p=0.000). In the AP fusion group, minimal clinically important difference (MCID) was reached in 47% of patients for back pain, 28% for leg pain, and 28% for Oswestry Disability Index (ODI). PSF had the highest percentage of patients reaching MCID for Short Form-36 (SF-36) physical composite score at 25%. ALIF and TLIF subgroups reached MCID for ODI in 17% of patients. Linear regression analysis showed that type of surgical approach did not impact change in ODI scores.

Keywords

- ► nonunion
- ► lumbar fusion
- outcomes
- ► revision spine surgery
- surgical approach

Conclusion Although not statistically significant, the AP fusion group reached MCID more frequently in all outcomes except SF-36 Physical Component Summary. All surgical approaches examined for treatment of lumbar pseudarthrosis resulted in only poor to modest improvement in ODI. This result further emphasizes the importance of achieving a solid fusion with the index surgery.

Introduction

Symptomatic lumbar nonunion remains a significant and difficult problem to treat. Failure rates as high as 40 to 70% have been reported following repeat fusion for pseudarthrosis. ^{1–4} Studies have also shown that patients with nonunion undergoing revision fusion surgery have worse outcomes compared with other indications for lumbar

fusion.^{5–8} Several surgical techniques exist for the treatment of nonunion, ranging from anterior-only and posterior-only procedures to combined anterior-posterior fusion. To our knowledge, there is no clear evidence in the literature as to which surgical technique is best suited for the treatment of symptomatic nonunion following attempted lumbar fusion.

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The different surgical approaches for treating lumbar pseudarthrosis have advantages and disadvantages. Posterior spinal fusion (PSF) and transforaminal lumbar interbody fusion (TLIF) provide the advantage of a single approach with the ability to examine the previous fusion mass directly and address any possible hardware failure issues. TLIF can offer the added advantage of additional anterior fusion surface area. Although anterior-posterior (AP) approach probably affords the most reliable chance of fusion, 2,4,6 it is associated with an increased complication rate. 9-12 Anterior lumbar interbody fusion (ALIF) alone can give the surgeon a large fusion surface area without further disruption of the paraspinal musculature.

Increasingly, treatment effectiveness for lumbar degenerative disorders is determined by improvements in healthrelated quality of life (HRQOL) measures. The most commonly used disease-specific measure for low-back pain is the Oswestry Disability Index (ODI), 13,14 and a commonly used generic measures is the Medical Outcomes Study Short Form-36 (SF-36). 15 Therefore, the purpose of the current study was to examine if different surgical techniques used for the treatment of lumbar nonunion impacts 2-year postoperative HRQOL measures.

Methods

After receiving Institutional Review Board approval, patients who underwent lumbar fusion surgery from 2002 to 2010 from a single institution for symptomatic nonunion who had preoperative and 2-year postoperative HRQOL measures were identified. Nonunion was diagnosed based on radiographs and computed tomography scans with sagittal and frontal reconstructions (>Fig. 1). HRQOLS evaluated included the SF-36, ¹⁵ the ODI, ^{13,14} and Numeric Rating Scales (0 to 10) for back and leg pain. 16 Patients were then grouped based on which surgical approach to treat their nonunion was used. Of the 134 patients identified, 60 patients underwent instrumented posterolateral fusion (PSF), 18 patients underwent PSF with TLIF, 32 patients underwent AP spinal fusion, and 24 patients underwent ALIF. The selection of surgical technique was based upon surgeon preference. All fusions were performed with instrumentation.

One-way analysis of variance was used to compare continuous variables, and the Kruskal-Wallis test was used to compare categorical variables among the four study groups. As the determination of which approach to use for the individual patients was based on physician preference, linear regression was also performed to control for confounders and selection bias. Factors included age, gender, number of levels, body mass index, smoking, and workers' compensation status as these factors have been previously shown to influence outcomes after lumbar fusion surgery. The primary outcome of interest was the 2-year ODI score. All statistical analyses were performed using Statistical Package for the Social Sciences version 21 (IBM, Somes, New York, United States). The percentage of patients reaching the minimum clinically important difference (MCID) was also examined for each group. This measure represents the minimum improvement in an outcome measure in which the patient perceives a worthwhile benefit. 17-20 The MCID was defined as 12.8-point decrease in ODI, 4.9-point increase in Physical Component Summary (PCS), 1.2-point decrease in back pain, and 1.6point decrease in leg pain based on previously published thresholds.²¹ Due to multiple concurrent analyses and relatively small sample size, threshold p value was set at 0.001.

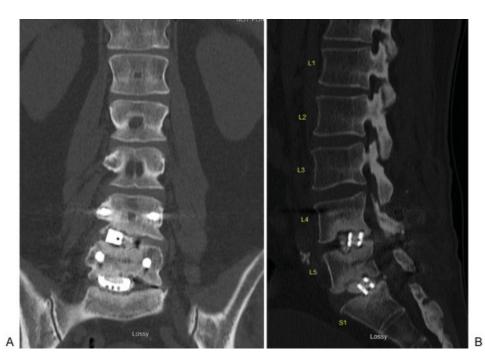


Fig. 1 (A) Frontal and (B) sagittal reconstructions of computed tomography axial scans of the 42-year-old man who had a transforaminal interbody fusion from L4 to S1 1 year prior showing lucency at the cage-end plate interface and lack of bridging trabeculation across the disk space.

Table 1 Summary of demographic data

	TLIF	AP	PSF	ALIF	Total	p Value
n	18	32	60	24	134	
Age (y)	51.89	52.69	49.5	48.22	50.37	0.485
No. of levels	1.28	1.44	1.42	1.33	1.39	0.631
Length of stay (d)	5.06	6.29	4.32	4.58	4.94	0.000
EBL (mL)	770.6	427.6	437.8	272.4	449.8	0.000
Operative time (min)	327.4	242.9	191.8	178.3	219.4	0.000
ВМІ	30.62	30.89	28.53	29.78	29.6	0.311
Males (n)	8	15	27	15	65	0.507
Smokers (n)	7	7	15	9	38	0.397
Workers' compensation (n)	3	5	5	4	17	0.625

Abbreviations: ALIF, anterior lumbar interbody fusion; AP, anteroposterior fusion; BMI, body mass index; EBL, estimated blood loss; PSF, posterolateral fusion; TLIF, transforaminal lumbar interbody fusion.

Results

The entire study cohort consisted of 65 male and 69 female patients with an average age of 50.4 years. Thirty-eight (28.4%) were smokers, and 17 (12.7%) were involved in a workers' compensation claim. Mean body mass index (BMI) was 29.6 kg/m². The average number of levels fused per patient was 1.39. The four groups were similar demographically in terms of age, sex distribution, smoking status, workers' compensation status, and BMI. The number of levels fused among the groups was similar as well. However, the TLIF group had a greater blood loss and longer operative time, and the AP group had a longer length of hospital stay compared with the other groups (~ Table 1).

Preoperative and 2-year HRQOL measures and the pre- to 2-year postoperative change in HRQOL measures for each of the surgical techniques are summarized in **-Table 2**. There were no significant differences between the treatment groups with regard to preoperative and 2-year HRQOL measures or the pre- to 2-year postoperative change in HRQOL measures. Although not statistically significant, PSF demonstrated the greatest improvement in all of the HRQOL measures at 2 years: 11.65-point improvement in ODI, 3.36-point improvement in SF-36 PCS, 2.19-point decrease in back pain, and 1.74-point decrease in leg pain.

We also examined the percentage of patients who reached the MCID for each surgical technique (**Fig. 2**). Only 17% of

Table 2 Summary of HRQOL

HRQOL	Time point	TLIF	AP	PSF	ALIF	p Value
ODI	Preoperative	57.73	58.97	50.94	61.96	0.007
	2-y	52.6	48.94	39.29	53.57	0.011
	Change	5.13	10.03	11.65	8.38	0.776
SF-36 PCS	Preoperative	27.71	26.83	28.65	26.51	0.421
	2-y	30.02	29.3	32.02	27.3	0.403
	Change	2.31	2.47	3.36	0.79	0.874
SF-36 MCS	Preoperative	28.01	35.46	35.7	30.17	0.132
	2-y	31.91	38.16	41.2	32.81	0.117
	Change	3.9	2.7	5.5	2.64	0.28
Back pain	Preoperative	7.78	8	8.08	8.14	0.899
	2-y	7.2	5.96	5.89	7.59	0.065
	Change	0.58	2.04	2.19	0.55	0.232
Leg pain	Preoperative	7.22	6.74	7	7.32	0.851
	2-year	7.67	5.88	5.26	7.53	0.013
_	Change	-0.44	0.86	1.74	-0.21	0.303

Abbreviations: ALIF, anterior lumbar interbody fusion; AP, anteroposterior fusion; HRQOL, health-related qualify of life; MCS, Mental Component Summary; ODI, Oswestry Disability Index; PCS, Physical Component Summary; PSF, posterolateral fusion; SF-36, Short Form-36, TLIF, transforaminal lumbar interbody fusion.

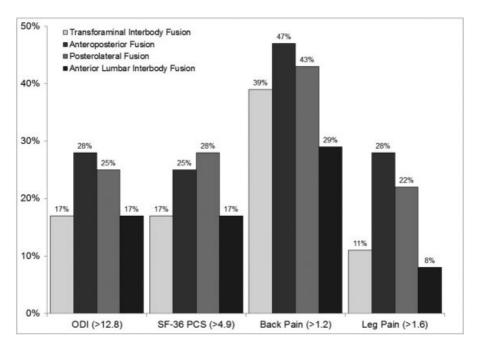


Fig. 2 Bar graph showing proportion of patients in each group achieving minimum clinically important differences for each of the outcome measures.²² Abbreviations: ODI, Oswestry Disability Index; PCS, Physical Component Summary; SF-36, Short Form-36.

patients reached the MCID for ODI when TLIF or ALIF were used to treat the nonunion. The MCID for ODI was reached in 25% of AP and 28% of PSF techniques. Back pain improved in 29 to 47% of patients reaching the MCID. The AP technique faired the best for all outcomes measured except for SF-36 PCS.

After controlling for factors such as age, gender, BMI, smoking status, workers' compensation status, number of levels fused, and preoperative HRQOL measures, the linear regression analysis showed that the type of surgical approach was not predictive of the change in any of the HRQOL scores (►Table 3).

Discussion

The primary goal of revision surgery for lumbar nonunion is to improve patients' symptoms and their quality of life.

Table 3 Summary of linear regression analysis with 2-year Oswestry Disability Index as the dependent variable of interest

Variable	Standardized beta coefficients	p Value
Age	0.00	0.987
Gender	0.01	0.934
Smoker	0.00	0.958
Number of levels fused	0.01	0.925
Weight	0.07	0.464
Workers' compensation	-0.04	0.591
Preoperative back pain	0.13	0.115
Preoperative leg pain	-0.02	0.839
Approach	-0.05	0.465

However, improvement after lumbar fusion surgery has been shown to be influenced by numerous factors unrelated to the technical success of the surgery. Albert et al found that the presence of abnormal neurologic findings, significant preoperative narcotic use, and workers' compensation or legal status before surgery increased the chance of failure.⁶

Although important, achieving a solid arthrodesis following pseudarthrosis may not be enough. The reported fusion rates after revision for nonunion have been highly variable, ranging from 40 to 100%.^{2,9,22,23} Despite the radiographic evidence of fusion success of 100% at 2 years, Adogwa et al found only a 4.01-point improvement in ODI at 2 years after surgery.²² Similarly, the study by Gertzbein et al also found a 100% union rate after circumferential fusion, but the satisfactory outcome rate was slightly better than 50% based on intensity of pain, pain medication use, and work status. In a prospective study of 18 patients undergoing revision for pseudarthrosis following PLIF with stand-alone cages, Cassinelli et al obtained a 94% fusion rate.²³ However, 72% of these patients rated their musculoskeletal condition as the same or worse compared with preoperative condition.

The mean ODI improvement in the current study was 9.71 points, which is better than previously published results. A previous study at our institution found only 5.5-point improvement in ODI at 2 years when treated with PSF alone.⁵ Cassinelli et al reported mean ODI improvement of 5.3 points.²³ In a subanalysis of their patients without a complication, ODI improved 10.2 points.

The purpose of this study was to determine if there was an optimal surgical treatment approach that not only achieves fusion after revision surgery for nonunion but also improves patient outcomes. Unfortunately, the type of surgical approach did not seem to impact patient outcomes, whether interpreted as a mean change in outcome scores or the proportion of patients achieving MCID. Even after controlling for possible confounding factors and selection bias, the type of surgical approach was not predictive of the change in any of the HROOL scores.

The present study is not without limitations. Although every patient included in this study had a lumbar pseudarthrosis, we did not stratify the different types of pseudarthrosis that may be encountered. For example, a patient might have had symptomatic adjacent-level stenosis but was found to have a pseudarthrosis intraoperatively. One could also argue that patients with gross instability and hardware failure might represent a subgroup of patients who are quite different from patients with a stable pseudarthrosis. Treating lumbar pseudarthrosis is, by nature, a complicated task. There can be a host of confounding variables that are both patient- and surgeon-related. Surgical indications for the index procedure can play an important role. Failed pseudarthrosis repair could potentially be due to improper diagnosis or indication for fusion in the first place.

In conclusion, this study found no statistically significant difference in HRQOL outcome measures between the four surgical techniques. The AP fusion group reached MCID more frequently in all outcomes except SF-36 PCS. All surgical approaches resulted in poor to modest improvement in ODI with 17 to 28% of patients reaching MCID for ODI. This study and previously published studies highlight the difficulty in achieving clinical success with revision surgery for lumbar pseudarthrosis, further emphasizing the importance of achieving a solid fusion with the index surgery.

Disclosures

R. Kirk Owens II: Employee of Norton Healthcare; receives payments for lectures from Alphatec. Medtronic provided funds directly to database company. No funds were paid directly to individual or individual's institution January 2002 to September 2009. Nuvasive provided funds directly to database company. No funds were paid directly to individual or individual's institution June 2012 to April 2015.

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Research Society. Medtronic provided funds directly to database company. No funds were paid directly to individual or individual's institution January 2002 to September 2009. Nuvasive provided funds directly to database company. No funds were paid directly to individual or individual's institution June 2012 to April 2015.

Steven D. Glassman: Employee of Norton Healthcare; received research grants from Norton Healthcare; holds patents from and receives royalties from Medtronic. Medtronic provided funds directly to database company. No funds were paid directly to individual or individual's Institution January 2002 to September 2009. Nuvasive provided funds directly to database company. No funds were paid directly to individual or individual's institution June 2012 to April 2015.

John R. Dimar II: Employee of Norton Healthcare; board member, Scoliosis Research Society; receives consulting fees from Medtronic and DePuy; receives payments for lectures from Medtronic, DePuy, and Norton Healthcare; holds patents from and receives royalties from Medtronic; is on the editorial review board of *JBJS Highlights, Spine, Spine Deformity, Journal of the American Academy of Orthopaedic Surgeons*, and *Global Spine Journal*. Medtronic provided funds directly to database company. No funds were paid directly to individual or individual's institution January 2002 to September 2009. Nuvasive provided funds directly to database company. No funds were paid directly to individual or individual's institution June 2012 to April 2015.

Leah Y. Carreon: Employee of Norton Healthcare; member, Editorial Advisory Board, Spine and Spine Journal; Institutional Review Board member, University of Louisville Institutional Review Board; Global Evidence Advisory Board member, Medtronic 2012, 2013; Research Committee member, Scoliosis Research Society; received research grants from Norton Healthcare and AO Spine paid directly to Scoliosis Research Society 2010 to 2011; receives research funds from the Orthopedic Research and Educational Fund, 2013 to present; received research grant from Norton Healthcare, 2013; receives Scoliosis Research Society Research Funding, 2013 to present; received research funding from the Norton Healthcare James R. Petersdorf Fund, 2015; received funds for travel for Study Planning Meetings from Orthopedic Educational Research Fund, Department of Defense, Association for Collaborative Spine Research, and the Center for Spine Surgery and Research of the University of Southern Denmark; received funds for travel for Annual required Continuing Education for Institutional Review Board members, University of Louisville Institutional Review Board; honoraria for participation in Review Panels National Institutes of Health, Children's Tumor Foundation, and Global Evidence Advisory Board, Medtronic. Medtronic provided funds directly to database company. No funds were paid directly to individual or individual's institution January 2002 to September 2009. Nuvasive provided funds directly to database company. No funds were paid directly to individual or individual's institution June 2012 to April 2015.

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